## REMARKS

Claims 1, 3-14 and 16-18 are pending and have been examined.

Claims 1, 3-6, 10-14 and 16-18 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite. The Office specifically is objecting to the term "substantially" in claims 1 and 17. Applicant submits that the term would have been understood by any person of ordinary skill in the art. The M.P.E.P. at § 2173.05(b)(D) indicates that this term is definite when one of skill would know what is meant or when general guidelines are contained in the specification. A specific definition of the term is not required to render "substantially" definite. The general guidelines in the specification, particularly at paragraph 13, which mentions that biologically active analogs, have sufficient amino acid homology with TA1 such that it functions in substantially the same way with substantially the same activity as TA1. This type of language is commonly used in the patent context and is well understood, particularly when the peptide in question is well-studied and its sequence and activity are known. Applicant requests reconsideration and withdrawal of this rejection.

Claims 1, 3-6, 10-14 and 16-18 are rejected as lacking sufficient written description under 35 U.S.C. § 112, first paragraph. Although the precise language in these claims deemed to lack written support is not defined, the Office has referred to the term "substantially" on page 7, line 1 of the Action. Applicant requests clarification of the language of the claims which is deemed to lack written support here if different from the term "substantially."

The Office states that it has given the term "substantially" its broadest reasonable interpretation. This interpretation is any peptide with any substitution at any or all of the 28 amino acids of the sequence. (The Office refers to "20 amino acids of thymosin alpha 1, however thymosin alpha 1 has 28 amino acids). Applicant therefore has amended the claims to clarify that the claimed sequences are those which consist of an amino acid sequence substantially similar to that of naturally occurring TA1. The language added to the claim is supported by the specification at paragraph 13.

Applicant submits that it is not reasonable to interpret the sequence to include numerous peptides that have no amino acids in common with TA1 as substantially similar.

Applicant submits that a skilled person would not reasonably interpret the claims to include any peptide of 28 amino acids as the Office has done here. Claims are to be interpreted in light of the specification as it would be interpreted by one of ordinary skill. See M.P.E.P. § 2111. The terms of these claims are supported by written description in the specification here and would be understood by the person of skill to include sequences with substantial similarity, and not all sequences with any substitution and any number of substitutions.

In making a prima facie case of lack of sufficient written description, the Office must provide reasons why a skilled person would not have recognized that the inventor was in possession of the invention as claimed. M.P.E.P. § 2163.04. The reasons given in the present Office Action are that the term "substantially" has been interpreted to indicate all possible substitutions of any or all amino acids. The reasons why this interpretation is not reasonable are discussed above. However, the breadth of a claim term is not relevant to whether the inventor possessed the invention. A person of skill would recognize that the inventor invented a method of treatment based on the activity of TA1 and would immediately believe that peptides of substantially similar amino acid sequence to TA1 that have bioactivity substantially similar to TA1 would work in the invention and were possessed at the time of filing. The members of the claimed genus are not of the enormity the Office asserts. Applicant submits that the broadest reasonable interpretation is far smaller than the broadest possible interpretation.

Another reason given by the Office is that the specification does not teach what bioactivity is necessary to perform the claimed function. The bioactivity of TA1, however, is well-known in the art. The specification clearly refers to the activity of TA1 and to immune stimulating-effective amounts. The skilled person knows what the activity of TA1 is, particularly with this guidance. Applicant is not required to describe background information that is known in the art. Therefore this reasoning is not

relevant to presenting a prima facie case here. As to the Office's contention that there is no correlation between structure and function, the claims require both substantially similar structure and substantially similar function. The person of skill knows both the structure and function of TA1, therefore the person of skill would easily conclude that peptides close enough in structure to have substantially the same bioactivity as TA1 would fall within the invention and were possessed by the inventor.

The Office then asserts that no examples for a method of making the invention are provided and that the specification refers to other documents "involving the use" of TA1. The claims do not encompass a method of making TA1 and therefore Applicant does not need to disclose methods of making when TA1 is so well-known in the art. The use is described in the specification itself, in terms of dosage and route of administration. Therefore, the applicant does not rely on extrinsic disclosures for any necessary disclosure. What is known in the art need not be disclosed again in a patent application. See M.P.E.P. § 2163(II)(1) ("The absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 U.S.C. § 112, para. 1, for lack of adequate written description.") The structure, function, and methods of making or isolating TA1 are known. The uses are described in the present specification. Therefore this also is not fair basis for a rejection for lack of written description.

The Office next states that word-for-word support in the specification is not an issue because the rejection is not a "new matter" rejection. Applicant submits, for the reasons discussed above, that the correlation between structure and function is a correlation between (1) substantial similarity in structure and the bioactivity of TA1 and (2) the inventive method. These structures and their bioactivity are made clear in the specification as a whole in view of the extensive art describing TA1, its structure and its function. A skilled person would be able to discern which peptides have TA1 bioactivity (which is well-known and for which well-known tests exist) and therefore what peptides fall within the claims.

Applicant therefore requests withdrawal of the rejection of the claims (as amended) on grounds of lack of written support.

Claims 1, 3-14 and 16-18 are rejected as not enabled under 35 U.S.C. § 112, first paragraph. The Office has enumerated the Wands factors, which Applicant will take in the same order here.

The Office has described the nature of the invention as encompassing all 20-mer [sic, 28-mer] peptides and any variant thereof, which, as discussed above is not a fair and reasonable claim interpretation.

The state of the art prior to the present invention was also described, using the post-filing references that are intended to show that there has been no consensus treatment for SARS treatment. These references however, are not relevant to the state of the art concerning TA1 peptides, their structures and their functions. Nor are these references relevant to the ease of following the direction provided in the specification with respect to how to use TA1 peptides to treat SARS or how to determine whether a peptide has TA1 bioactivity or how to discern whether a SARS treatment has been unsuccessful.

Specifically, Holmes relates to antiviral agents, of which TA1 is not an example. A prediction that drugs/vaccines may take time to develop, published before the present invention was published, is irrelevant to the issue which the Office brings to this rejection. Fujii and Stockman discuss treatments for SARS other than what is invented here. References showing the failure of others using different and even unrelated methods of treatment, and which do not even mention TA1, serve only to demonstrate the unexpected and important nature of the present invention. Furthermore, each reference was written prior to or near the publication of the present application and therefore these authors were not aware of the present teachings. Their discussion therefore is not relevant here.

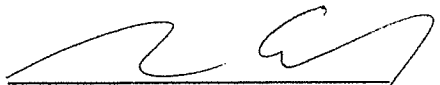
With respect to the breadth of the claims, the Office repeats its interpretation of the term "substantially," which has been discussed above and refers to Holmes for a list of coronaviruses. Applicant submits the claims are not as broad as the Office asserts.

The presence or absence of working examples is not relevant to enablement as long as the skilled person would be able to perform the method claimed. Applicant submits that the specification contains sufficient guidance for the artisan to perform the treatment of the claims as amended. Other references discuss failure with other types of agents, but nothing in the cited art casts any doubt upon TA1's effectiveness.

The Office's point concerning the amount of experimentation which would be necessary also is based on the interpretation of the claims as encompassing all 28-mer peptides and not only those which would have been recognized by skilled artisans as having a substantially similar amino acid sequences. Therefore, the amount of experimentation actually required is far smaller than the Office asserts and is not undue, since testing for TA1 bioactivity is simple and routine and was so at the time of filing. As the Office Action quotes, the key word is "undue." Action at page 17, line 15. There is no evidence presented here that indicates undue experimentation would be required here.

For the above reasons, Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, relating to written description and enablement and reconsideration of each claim now presented here.

Respectfully submitted,

By: 

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